Robert W. Boatman (009619) - rwb@gknet.com
Paul L. Stoller (016773) - paul.stoller@gknet.com
Shannon L. Clark (019708) – slc@gknet.com
Gallagher & Kennedy, P.A.
2575 East Camelback Road
Phoenix, Arizona 85016-9225
602-530-8000

Ramon Rossi Lopez - rlopez@lopezmchugh.com
California Bar Number 86361 - admitted *pro hac vice*
Lopez McHugh LLP
100 Bayview Circle, Suite 5600
Newport Beach, California 92660
949-812-5771

Co-Lead/Liaison Counsel for Plaintiffs

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION

No. MD-15-02641-PHX-DGC

RESPONSE TO DEFENDANTS' NOTICE OF SUPPLEMENTAL INFORMATION REGARDING FDA INSPECTION AND WARNING LETTER

Gallagher & Kennedy, P.A.
2575 East Camelback Road
Phoenix, Arizona 85016-9225
(602) 530-8000

On March 4, 2016, Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. filed a Notice of Supplemental Information Regarding FDA Inspection and Warning Letter ("Notice") [Doc. 989]. Therein, they notify the Court that the Food and Drug Administration ("FDA") has issued two more Form 483 Letters (letters that specify actionable conditions identified during FDA inspections) to Defendants arising out of recent inspections of their IVC filter facilities. Defendants contend that these newest FDA allegations have "little" relevance but admit they "may warrant a short follow-up Rule 30(b)(6) deposition." Notice at 2. Defendants' casual minimization of the relevance of the FDA's concerns with and scrutiny of Bard's IVC filters notwithstanding, these new events further demonstrate why this Court should not preclude Plaintiffs from taking discovery regarding the FDA's investigations, communications, and conclusions (including the violations found in the Warning Letter) regarding Defendants' IVC filters and facilities.

The FDA issued the two newest Form 483 Letters to Defendants on February 26, 2016 and March 2, 2016.[1] The first letter identifies two separate "observations," both of which relate to Defendants' collection and reporting of "complaint rates." While Defendants suggest that the FDA's concern has solely to do with the "written procedure" for complaint trending [Notice at 2], the FDA actually criticizes Defendants' calculation methodology and finds that Defendants did not actually perform certain reviews despite Defendants' claim to having done so.[2] Contrary to Defendants' contentions, this is not a mere documentation issue. Rather, the FDA appears to have discovered yet another instance of inaccurate (and possibly false) reporting by Defendants regarding adverse event complaints for IVC filters.

As discussed in Plaintiffs' Memorandum Regarding Relevancy and Discoverability of FDA Inspection and Warning Letter and Recovery Cone Removal System ("Memorandum") [Dkt. No. 697], Defendants' inaccurate and under-reporting of complaint- and failure rates for its IVC filters to the FDA and to the public at large (through the MAUDE database) is relevant to virtually every claim in the Master Complaint. Reporting and publication of accurate failure rates for Defendants' IVC filters are directly relevant to the safety of those products and liability under both the risk-benefit and consumer-expectations tests for Plaintiffs' product-liability claims. Those rates also relate to the reasonableness of Defendants' actions in the design of their devices and the warnings given about them. Moreover, Plaintiffs and their physicians rely on the publicly reported information from Defendants. To the extent that Defendants have misreported (or under-reported) adverse event information, those actions are relevant to Plaintiffs' claims for failure to warn, fraud, misrepresentation, state statutory consumer fraud and

[1] Defendants produced the two Form 483 Letters to Plaintiffs on March 11, 2016. Defendants have produced no other information relating to the letters or the FDA inspections that culminated in them.

[2] The second Observation concludes that not all complaint files had been adequately reviewed and that, even though the complaint files indicated Defendants had performed an Early Detection Systems (EDS) review, such a review could not have been performed because there was no data to provide the numerator for such calculations.

deceptive practices actions, and punitive damages.[3] And, the facts bear on several of Defendants' affirmative defenses, including the Learned Intermediary doctrine, adequacy of warnings, and acceptance of risk, among others.

The second Form 483 Letter appears, on its face, to relate to Defendants' failure to perform certain tests in accordance with required protocols. This failure relates to at least six generations of IVC filters at issue in this MDL – Recovery, G2, G2X, Eclipse, Meridian, and Denali. At this point, Plaintiffs simply cannot determine one way or another whether the FDA's findings on these issues are relevant. It is possible that Defendants' testing failures relate to the design issues with respect to virtually all of the filters in this litigation; or, the testing failures could be utterly irrelevant. Defendants suggest the failures relate to filter cleanliness inspections and that "[n]othing in the Letter suggests that the alleged deficiency impacts the integrity of Bard's IVC filters or otherwise impacts Plaintiffs' manufacturing defect claims." Notice at 2. But, they provide no evidence to support that claim, and only discovery can provide Plaintiffs the evidence to determine whether that is the case.

No prior discovery has been taken on these matters (in this MDL, the pre-MDL cases, or any state-court case). Plaintiffs should have the opportunity to discover the facts relating to the FDA's inspections, findings, and actions with respect to the filters at issue in this MDL. Like the prior FDA Form 483 Letters and the Warning Letter, these most recent actions by the FDA relate to the filters at issue in this MDL and are relevant to the claims in the Master Complaint.

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[3] Again, Defendants appear to suggest that their internal reporting "is most important." Notice at 2-3. But, as noted in Plaintiffs' Memorandum [10-11], Bard does not share its internal information and rates with the public or the FDA. And, patients and their physicians rely on the accuracy of the publicly reported information. Thus, both the internal and the external reporting by Defendants are relevant.

RESPECTFULLY SUBMITTED this 18th day of March 2016.

GALLAGHER & KENNEDY, P.A.

By: */s/ Robert W. Boatman*
Robert W. Boatman
Paul L. Stoller
Shannon L. Clark
2575 E. Camelback Road, Suite 1100
Phoenix, Arizona 85016-9225
LOPEZ McHUGH LLP
Ramon Rossi Lopez (CA Bar No. 86361)
(admitted *pro hac vice*)
100 Bayview Circle, Suite 5600
Newport Beach, California 92660

Co-Lead/Liaison Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on this 18th day of March, 2016, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Nancy Jo Koenes

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